Background information on MON863. Greenpeace, September 2004

Monsanto's GM corn: Unfit for rats, unfit for humans

1. Serious safety concerns

MON863 is a genetically modified corn which expresses a Bt-toxin (Cry3Bb1). This toxin, which stems from a micro-organism (*Bacillus thuringiensis*), is meant to protect the maize against a pest called corn rootworm. This GM maize is different from those Bt-plants (Mon 810, Bt11, Bt 176) already placed on the market, as they produce another toxin (Cry1Ab), which is toxic to the European corn borer.

On 23 April 2004, French newspaper Le Monde revealed that the French expert body in charge of GMO evaluation (CGB-Commission du Génie Biomoléculaire) had expressed doubts about the safety of GM maize Mon 863. Its expertise had remained confidential and was based on a rat feeding trial study which the CGB had requested from the applicant. This study showed that "significant variations" were found between the rats fed with conventional maize and those fed with GM maize Mon863, such as an increased number of white blood cells in the males, reduced immature red blood cells in females, a significant increase in blood sugar in the females or a higher frequency of physical irregularities in the kidneys of the males, such as reduced weight and inflammation.

On 5 May 2004, Greenpeace wrote to the German Agriculture Ministry, which was in charge of the initial risk assessment report, to ask for an examination of the records concerning Mon 863. On 4 August, the German Agriculture Ministry replied that the applicant, Monsanto, had refused to agree to publish the initial rat study MSL-18175, which had been classified as "confidential business information". Instead, Greenpeace was sent a new study, "Supplemental analysis of selected findings on the rat 90-day feeding study with MON863 maize".

On 11 September 2004, a report in German newspaper Frankfurter Allgemeine Sonntagszeitung stated that two French experts had re-checked Monsanto's data, and come to the result that the experiments did not show that Mon863 is unsafe.

Greenpeace's own detailed examination of the material provided by Monsanto, however, gives enough reasons for further concerns.

The paper from Monsanto reveals many irregularities in the study and five significant differences between the rats fed with the GMO maize and the control groups.

These include statistically significant differences in white blood cells. These cells are an indicator of abnormal situations in the body such as infections and inflammations. Furthermore, there are differences in the organ weight of the kidneys and some abnormal changes in the structure of the kidneys.

Monsanto tries to negate these findings by use of "reference" and "historical" control data collected from other experiments where rats were fed non-GM maize. Such inclusion of "historical" or "reference" data is not valid from a scientific point of view. It is the direct comparison between two or more groups during a certain experiment that is the critical and valid comparison in normal scientific practices. As soon as statistically significant differences appear, one should immediately check for further evidence, run further experiments to try to find out where those differences come from. This is particularly important as this feeding trial was only conducted over 90 days. The high number of statistically significant differences therefore raises severe doubts regarding the food and feed safety of this GMO maize.

Since the study clearly indicates that this GM maize has the potential to cause negative effects on the health of rats, it could also interfere with the metabolism of humans and animals. This is a clear reason for rejecting the request for market permission.

Furthermore, the whole experiment lacks good design. Important data and parameters are missing - at least in the summary that was provided by Monsanto. And as the whole experiment only took 90 days, it remains impossible to draw any conclusions regarding long-term ingestion of the maize.

The high number of statistically significant differences between rats fed MON863 and the control groups in this short feeding trial should be cause for concern and MON863 should be rejected outright.

2. Lack of transparency

Greenpeace believes that the German authorities have breached the requirement of “Directive 2001/18/EC on the deliberate release of GMOs in the environment” by agreeing to classify as “confidential” a feeding study which is part of the environmental and human health risk assessment and which does not contain information pertaining to innovative research, new techniques or methods.

Article 25 of Directive 2001/18/EC states that :

2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position and which should therefore be treated as confidential. Verifiable justification must be given in such cases.
3. The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions.”

Article 25 (4) also indicates that “in no case” should the information related to “environmental risk assessment” be kept confidential.

Article 2 (8) of Directive 2001/18 defines “environmental risk assessment” as “the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II.”

In Annex II the general principles declare that the risk assessment should : "be carried out in a scientifically sound and transparent manner based on available scientific and technical data".

Conclusion: Lack of transparency undermines the Directive's principle of openness and prevents effective public scrutiny. The high number of statistically significant differences between rats fed high-dose MON863 and the controls in the 90 days feeding trial should be cause for concern and MON863 authorisation should be rejected.

Although the legal requirements for GMO evaluation in the EU were tightened up with Directive 2001/18/EC, the practical evaluation conducted by national competent authorities is still characterised by a lack of transparency and a lack of rigorous scrutiny of the applications in most member states. In practical terms, the evaluation of GMO applications during the last year has showed no improvement compared to the old pre-“moratorium” system.